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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,432	12/10/2003	Helmut D. Link	246472003920	5128
25227 7590 03/02/2007 MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			03/02/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,432	<b>Applicant(s)</b> LINK ET AL.	
	<b>Examiner</b> Richard R. Shaffer	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The amended drawings filed on December 7<sup>th</sup>, 2006 are acknowledged and accepted by the examiner. The corresponding objections are hereby withdrawn.

### ***Claim Objections***

Applicant's remarks filed on December 7<sup>th</sup>, 2006 are acknowledged. The previous objection to claim 13 is hereby withdrawn.

However, the new claims filed on December 7<sup>th</sup>, 2006 are objected to. Applicant has intended to add claims 24 and 25, however has listed the two new claims both "24." For purposes of examination, the second claim 24 will be treated as claim 25.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has added the limitation, "a width of the intervertebral plate being at least about 70% of the width of the intervertebral space" to claims 18 and 24.

Applicant's disclosure states, "Its dimensions in the AP direction and LM direction (LM =

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lateral-medial, i.e. perpendicular to the median plane) are not significantly smaller than those of the intervertebral space. It should be at least 70% of the clear distance between the protrusions of the lower vertebral body, preferably at least 80%."

Therefore, applicant does not have support for a "width" but rather either an AP or LM direction, and can not claim at least 70% of the "vertebral space" when the 70% corresponds to the clear vertebral space. The limitation will be considered only as far as a dimension of the plate needs to be "about" 70% of a deemed "clear vertebral space."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-18, 20, 23, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Patent 6,159,214). Michelson discloses a system comprising:

**[First Interpretation]** a guide device (700) has a moveable opening for guiding a tool; an adjustment instrument having a rod (152), a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space, and an intermediate adjustment portion (758); the adjustment portion (758) is displaceable

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along the rod (152) with the use of the grooves (156); the moveable opening of the guide device (700) is larger than the intervertebral plate (154); and the tip of the plate (154), the shoulder of plate that juts out from the rod (152), and bores (155, 714, 720a-b, and 721a-d) can all act as x-ray markers.

**[Second Interpretation]** a guide device (700) has a moveable opening for guiding a tool; an adjustment instrument having a rod (152, 758) and a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space; the guide device can be pushed onto a free end of the adjustment rod (152, 758) with engagement features (737a and 723a) creating a non-rotational fit; the drill guide further has four drill gauges (721a-d) with two pairs offset by 180 degrees; the guide device (700) could be rotated by 180 degrees while maintaining functionality; the shoulder of plate that juts out from the rod (152), and bores (155, 714, 720a-b, and 721a-d) can all act as x-ray markers.

**[Third Interpretation]** a guide device (1110) has a moveable opening for guiding a tool; an adjustment instrument having a rod (152) and a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space; the guide device (1110) defines at least guide holes (1130, 1132, as well as unlabeled portions) to receive pins (1228a-b like shown in **Figure 68**); and a spreader (1100) that can hold maintain the pins parallel to one another.

The method Michelson disclosed can be found in **Column 5, Line 19 through Column 6, Line 36**.

In regard to claim 20, **Column 16, Lines 16-21 and Column 22, Lines 1-4** describe that rasps in a variety of shapes and lengths are anticipated in combination with the device disclosed.

Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al (US Patent 7,025,787).

Bryan et al disclose a method (**Figures 22-38B**) for fitting an intervertebral prosthesis (**102**) comprising: removing an intervertebral disc (**Figure 22**); positioning and securing an intervertebral plate (**302**) in the intervertebral space (**Figure 24**); pushing a hub (**316**) of a guide device (**318**) onto an adjustment rod (**308**); the guide device defining two guide axes (**314**) above and below the adjustment rod and parallel thereto; introducing two pins (**332, Column 20, Lines 29-42**) into the vertebral bodies in the direction of the guide axes; then connecting a distraction forceps (**344**) to the pins that apply a force thereby helping the hold the pins parallel thereby also setting a spacing of the intervertebral bodies; removing the adjustment rod (**Column 21, Lines 1-5**); working the intervertebral space and fitting the intervertebral prosthesis in the space (**Column 21, Line 50 through Column 22, Line 61**).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Jacobson (US Patent 4,545,374).

Michelson discloses all of the claimed limitations except is silent as to whether x-ray monitoring is used while introducing the intervertebral plate. Jacobson teaches (**Column 2, Lines 46-49**) that using fluoroscopic x-ray, it insures proper placement and maneuvering of instruments. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Michelson under x-ray monitoring to minimize possible surgical error in placement and movement of instruments.

### ***Response to Arguments***

Applicant's arguments filed December 7<sup>th</sup>, 2006 have been fully considered but they are not persuasive. Applicant first argues that any portion of the intervertebral plate of Michelson could not be used as an X-ray marker for positioning. In the medial-lateral direction, no portion of Michelson's device would block the line of sight of the X-ray image as shown in **Figure 11D** therefore allowing the entire length of the plate (which extends lengthwise along the anterior-posterior direction) to act as an X-ray marker.

Applicant further argues that the limitation, "has a size and shape adapted to allow the plate to adopt a position that is generally centered with respect to the intervertebral space" is not anticipated by Michelson. The size of the plate of Michelson is clearly able to adopt a centered position in the intervertebral space because it is small enough to fit in the space. The device can be placed in any position, including the center.

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The limitation of at least 70% of a dimension of the clear vertebral space, as shown in **Figure 11D**, one can see the dimension shown is at least 70% of the disc space. Further, applicant's argument that the new limitation of a smooth surface is not found persuasive. Applicant describes smooth as being "without elevations." Clearly, the plates as shown in both **Figures 11B and 11C** are "without elevations" to avoid sinking into the bone or cartilage surface.

In regard to claim 16, applicant states that Michelson does not disclose a non-rotational fit. Previously (Second Interpretation), it was made clear that in regards to the non-rotational fit, the adjustment rod was both elements **152** and **758** with a guide device **700**. Engagement features **737a** (from the rod) and **723a** from the guide having complementary shapes to prevent rotation.

In regard to applicant's argument with respect to claim 20, the reason the disclosure is vague is because a plurality of implants do exist and therefore would require different shapes or lengths to remove the appropriate amount of bone. It is inherent that the largest bone removal means would correspond very closely to the shape, else too much or too little of bone material would be removed.

Applicant's arguments with respect to claim 22 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

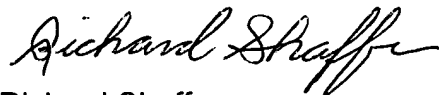
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
February 26<sup>th</sup>, 2007



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SUPERVISORY PATENT EXAMINER